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DOCKET NO.: P453.70115US01

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Sanghvi et al.  
Serial No.: 10/821,811  
Confirmation No.: Not Yet Assigned  
Filed: April 8, 2004  
For: PHARMACEUTICAL FORMULATION  
  
Examiner: Not Yet Assigned  
Art Unit: Not Yet Assigned

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CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)

The undersigned hereby certifies that this document is being placed in the United States mail with first-class postage attached, addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the 16 day of June, 2004.

Kristin J. Ketelhut  
Kristin J. Ketelhut

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Commissioner For Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Transmitted herewith are the following documents:

- ☒ Information Disclosure Statement
- ☒ PTO Form 1449 with cited references
- ☒ Return Receipt Postcard

If the enclosed papers are considered incomplete, the Mail Room and/or the Application Branch is respectfully requested to contact the undersigned at (617) 646-8000, Boston, Massachusetts.

A check is not enclosed. If a fee is required, the Commissioner is hereby authorized to charge Deposit Account No. 23/2825. A duplicate of this sheet is enclosed.

Respectfully submitted,  
*Sanghvi et al., Applicant*

By: Edward R. Gates  
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Docket No. P453.70115US01  
Date: June 16, 2004  
x07/08/04x



DOCKET NO: P0453.70115US01

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

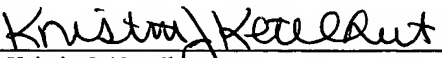
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Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

STATEMENT FILED PURSUANT TO THE DUTY OF  
DISCLOSURE UNDER 37 CFR §§1.56, 1.97 AND 1.98

Sir:

Pursuant to the duty of disclosure under 37 C.F.R. §§1.56, 1.97 and 1.98, the Applicant requests consideration of this Information Disclosure Statement.

PART I: Compliance with 37 C.F.R. §1.97

This Information Disclosure Statement has been filed within three months of the filing date of a National Application other than a continued prosecution application under 37 C.F.R. §1.53(d).

No fee or certification is required.

**PART II: Information Cited**

The Applicant hereby makes of record in the above-identified application the information listed on the attached form PTO-1449 (modified). The order of presentation of the references should not be construed as an indication of the importance of the references.

The Applicant hereby makes the following additional information of record in the above-identified application.

The Applicant would like to bring to the Examiner's attention the following co-pending applications that may contain subject matter related to this application:

<u>Docket No.</u>	<u>Serial No.</u>	<u>Filing Date</u>	<u>Inventor(s)</u>
P0453.70109US00	10/163,482	June 5, 2002	Moss et al.
P0453.70110US00	10/278,630	October 23, 2002	Foss et al.
<sup>1</sup> P0453.70110US01	10/779,129	February 12, 2004	Foss et al.
P0453.70112US01	10/821,813	April 8, 2004	Boyd et al.
P0453.70113US00	10/357,669	February 4, 2003	Foss et al.
<sup>2</sup> P0453.70113US01	10/779,128	February 12, 2004	Foss et al.
<sup>2</sup> P0453.70113US02	10/778,268	February 12, 2004	Foss et al.
<sup>2</sup> P0453.70113US03	10/785,320	February 12, 2004	Foss et al.
<sup>2</sup> P0453.70113US04	10/785,668	February 24, 2004	Foss et al.
P0453.70114US00	10/358,560	February 5, 2003	Foss et al.
P0453.70116US01	10/821,809	April 8, 2004	Sanghvi et al.

<sup>1</sup>Copy not enclosed; see P0453.70110US00, Serial No. 10/278,630 for identical specification

<sup>2</sup>Copy not enclosed; see P0453.70113US00, Serial No. 10/357,669 for identical specification

The following are remarks concerning the other information cited:

**PART III: Remarks**

Documents cited anywhere in the Information Disclosure Statement are enclosed unless otherwise indicated. It is respectfully requested that:

1. The Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims;
2. The enclosed form PTO-1449 be signed by the Examiner to evidence that the cited information has been fully considered by the Patent and Trademark Office during the examination of this application;
3. The citations for the information be printed on any patent which issues from this application.

By submitting this Information Disclosure Statement, the Applicant makes no representation that a search has been performed, of the extent of any search performed, or that more relevant information does not exist.

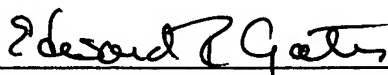
By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. §1.56(b).

By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 U.S.C. §102.

Notwithstanding any statements by the Applicant, the Examiner is urged to form his own conclusion regarding the relevance of the cited information.

An early and favorable action is hereby requested.

Respectfully submitted,  
Sanghvi et al., *Applicant*

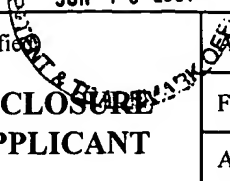
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Telephone: (617) 646-8000

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Date: June 16, 2004

**X07/08/04X**

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FORM PTO-1449/A and B (Modified)  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>			APPLICATION NO.: 10/821,811	ATTY. DOCKET NO.: P0453.70115US01	
FILING DATE: April 8, 2004			CONFIRMATION NO.: Not Yet Assigned		
APPLICANT: Sanghvi et al.			EXAMINER: Not Yet Assigned		
GROUP ART UNIT: Not Yet Assigned			EXAMINER: Not Yet Assigned		
Sheet	1	of	6		

#### U.S. PATENT DOCUMENTS

Examiner's Initials	Cite No.	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication or of issue of Cited Document MM-DD-YYYY
		Number	Kind Code		
	A1	2001/0018413	A1	Crain, <i>et al.</i>	08-30-2001
	A2	2002/0028825	A1	Foss, <i>et al.</i>	03-07-2002
	A3	2001/0033865	A1	Oshlack, <i>et al.</i>	10-25-2001
	A4	2001/0036476	A1	Oshlack, <i>et al.</i>	11-01-2001
	A5	2001/0047005	A1	Farrar, <i>et al.</i>	11-29-2001
	A6	4,176,186		Goldberg, <i>et al.</i>	11-27-1979
	A7	4,719,215		Goldberg	01-12-1988
	A8	4,861,781		Goldberg	08-29-1989
	A9	4,987,136		Kreek, <i>et al.</i>	01-22-1991
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	A11	5,270,328		Cantrell, <i>et al.</i>	12-14-1993
	A12	5,472,943		Crain, <i>et al.</i>	12-05-1995
	A13	5,512,578		Crain, <i>et al.</i>	04-30-1996
	A14	5,767,125		Crain, <i>et al.</i>	06-16-1998
	A15	5,811,451		Minoia, <i>et al.</i>	09-22-1998
	A16	5,866,164		Kuczynski, <i>et al.</i>	02-02-1999
	A17	5,958,452		Oshlack, <i>et al.</i>	09-28-1999
	A18	5,972,954		Foss, <i>et al.</i>	10-26-1999
	A19	6,096,756		Crain, <i>et al.</i>	08-01-2000
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	A23	6,395,705	B2	Crain, <i>et al.</i>	05-28-2002
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	A25	6,451,806	B2	Farrar	09-17-2002
	A26	6,559,158	B1	Foss, <i>et al.</i>	05-06-2003
	A27	6,608,075	B1	Foss, <i>et al.</i>	08-19-2003
	A28	RE36,547		Crain, <i>et al.</i>	02-01-2000
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#### FOREIGN PATENT DOCUMENTS

Examiner's Initials	Cite No.	Foreign Patent Document			Name of Patentee or Applicant of Cited Document (not necessary)	Date of Publication of Cited Document MM-DD-YYYY	Translation (Y/N)
		Office/ Country	Number	Kind Code			
	B1	AU	610,561		Shelley	08-17-1988	
	B2	CA	1,315,689		The University of Chicago	04-06-1993	
	B3	EP	0278821	A1	Shelly (Abstract)	08-17-1988	

<b>FORM PTO-1449/A and B (Modified)</b>  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>				APPLICATION NO.: 10/821,811		ATTY. DOCKET NO.: P0453.70115US01	
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	B5	EP	278,821	A1	Marc Yves Shelly (Derwent Abstract)	08-17-1988	
	B6	EP	306,575	B1	The Univ. of Chicago	03-15-1989	
	B7	EP	352,361	A1	The Rockefeller University	01-31-1990	
	B8	EP	760,661	B1	Minoia, <i>et al.</i>	12-30-1998	
	B9	JP	2,625,457	B2	Goldberg (Derwent Abstract)	07-02-1997	
	B10	NZ	222,911		The Univ. of Chicago	12-14-1987	
	B11	WO	83/03197	A1	The Rockefeller University	09-29-1983	
	B12	WO	88/05297	A1	Shelly	07-28-1988	
	B13	WO	95/31985	A2	Minoia, <i>et al.</i>	11-30-1995	
	B14	WO	97/33566		Alza Corp.	09-18-1997	
	B15	WO	98/25613		Klinge Pharma GmbH	06-18-1998	Yes
	B16	WO	01/13909	A2	Critical Care Pharm.	03-01-2001	
	B17	WO	01/37785	A2	Adolor Corp.	05-31-2001	
	B18	WO	01/41705	A2	Adolor Corp.	06-14-2001	
	B19	WO	01/42207	A2	Adolor Corp.	06-14-2001	
	B20	WO	01/85257	A2	Pain Therapeutics, Inc..	11-15-2001	
	B21	WO	02/060870	A2	Adolor Corp.	08-08-2002	

#### OTHER ART — NON PATENT LITERATURE DOCUMENTS

Examiner's Initials	Cite No	Include name of the author (in CAPITAL LETTERS) title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, relevant page(s), volume-issue number(s), publisher, city and/or country where published.	Translation (Y/N)
	C1	AKINBAMI et al., Effect of a peripheral and a central acting opioid antagonist on the testicular response to stress in rats. <i>Neuroendocrinology</i> . 1994 Apr;59(4):343-8.	
	C2	AMIN et al., Efficacy of methylnaltrexone versus naloxone for reversal of morphine-induced depression of hypoxic ventilatory response. <i>Anesth Analg</i> . 1994 Apr;78(4):701-5.	
	C3	AMIR, Naloxone improves, and morphine exacerbates, experimental shock induced by release of endogenous histamine by compound 48/80. <i>Brain Res</i> . 1984 Apr 9;297(1):187-90.	
	C4	AMIR et al., Endorphins in endotoxin-induced hyperglycemia in mice. <i>Arch Toxicol Suppl</i> . 1983;6:261-5.	
	C5	ARGENTIERI et al., Interaction of the opiate antagonist, naltrexone methyl bromide, with the acetylcholine receptor system of the motor end-plate. <i>Brain Res</i> . 1983 Oct 31;277(2):377-9.	
	C6	BARATTI et al., Brain opioid peptides may participate in the reversal of pentylene-tetrazol-induced amnesia. <i>Methods Find Exp Clin Pharmacol</i> . 1990 Sep;12(7):451-6.	
	C7	BEDINGFIELD et al., Methylnaltrexone attenuates taste aversion conditioned by low-dose ethanol. <i>Alcohol</i> . 1998 Jan;15(1):51-4.	
	C8	BIANCHETTI et al., Quaternary derivatives of narcotic antagonists: stereochemical requirements at the chiral nitrogen for in vitro and in vivo activity. <i>Life Sci</i> . 1983;33 Suppl 1:415-8.	
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	C12	BRIX-CHRISTENSEN et al., Endogenous morphine is produced in response to cardiopulmonary bypass in neonatal pigs. <i>Acta Anaesthesiol Scand</i> . 2000 Nov;44(10):1204-8.	
	C13	BROWN et al., Opiate antagonists: central sites of action in suppressing water intake of the rat. <i>Brain Res</i> . 1981 Sep 28;221(2):432-6.	

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Sheet	3	of	6				

	C14	BROWN et al., Reversal of morphine-induced catalepsy in the rat by narcotic antagonists and their quaternary derivatives. <i>Neuropharmacology</i> . 1983 Mar;22(3):317-21.		
	C15	BROWN et al., The use of quaternary narcotic antagonists in opiate research. <i>Neuropharmacology</i> . 1985 Mar;24(3):181-91. Review.		
	C16	CALCAGNETTI et al., Quaternary naltrexone reveals the central mediation of conditional opioid analgesia. <i>Pharmacol Biochem Behav</i> . 1987 Jul;27(3):529-31.		
	C17	CHANG et al., An antiabsorptive basis for precipitated withdrawal diarrhea in morphine-dependent rats. <i>J Pharmacol Exp Ther</i> . 1984 Feb;228(2):364-9.		
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	C20	FERNANDEZ-TOME et al., Interaction between opioid agonists or naloxone and 5-HTP on feeding behavior in food-deprived rats. <i>Pharmacol Biochem Behav</i> . 1988 Feb;29(2):387-92.		
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	C36	KAUFMAN et al., Role of opiate receptors in the regulation of colonic transit. <i>Gastroenterology</i> . 1988 Jun;94(6):1351-6.		
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	C39	KOBLISH et al., Behavioral profile of ADL 8-2698, a novel GI-restricted $\mu$ opioid receptor antagonist. <i>Society for Neuroscience Abstracts</i> . 2001;27(2):2407.		
	C40	KOBYLECKI et al., N-Methylnalorphine: definition of N-allyl conformation for antagonism at the opiate receptor. <i>J Med Chem</i> . 1982 Nov;25(11):1278-80.		
	C41	KOCZKA, et al., <i>Acta Chimica Academica Scien. Hung.</i> (1967) 51(4), 393-02		

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Sheet	4	of	6				

C42	KOOB et al., Effects of opiate antagonists and their quaternary derivatives on heroin self-administration in the rat. <i>J Pharmacol Exp Ther.</i> 1984 May;229(2):481-6.		
C43	KOTAKE et al., Variations in demethylation of N-methylnaltrexone in mice, rats, dogs, and humans. <i>Xenobiotica.</i> 1989 Nov;19(11):1247-54.		
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C45	KROMER et al., The current status of opioid research on gastrointestinal motility. <i>Life Sci.</i> 1989;44(9):579-89. Review.		
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C53	MANARA et al., The central and peripheral influences of opioids on gastrointestinal propulsion. <i>Annu Rev Pharmacol Toxicol.</i> 1985;25:249-73. Review.		
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C55	MISRA et al., Intravenous kinetics and metabolism of [15,16-3H]naltrexonium methiodide in the rat. <i>J Pharm Pharmacol.</i> 1987 Mar;39(3):225-7.		
C56	MOERMAN et al., Evaluation of methylnaltrexone for the reduction of postoperative vomiting and nausea incidences. <i>Acta Anaesthesiol Belg.</i> 1995;46(3-4):127-32.		
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C61	MURPHY et al., Pharmacokinetic profile of epidurally administered methylnaltrexone, a novel peripheral opioid antagonist in a rabbit model. <i>Br J Anaesth.</i> 2001 Jan;86(1):120-2.		
C62	MURPHY et al., American Society of Anesthesiologists 1999 annual meeting. Dallas, Texas, USA. October 9-13, 1999. Abstracts. <i>Anesthesiology.</i> 1999 Sep;91(3A Suppl):A349.		
C63	MURPHY et al., Opioid-induced delay in gastric emptying: a peripheral mechanism in humans. <i>Anesthesiology.</i> 1997 Oct;87(4):765-70.		
C64	MURPHY et al., Opioid antagonist modulation of ischaemia-induced ventricular arrhythmias: a peripheral mechanism. <i>J Cardiovasc Pharmacol.</i> 1999 Jan;33(1):122-5.		
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C66	NELSON, Dissertation Abstracts International, (62/03-B), p. 1635 (Abstract)		
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#EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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